Exhibit F

PEGGY PENCE, PhD, RAC, FRAPS
EXPERT WITNESS REPORT

RE: MODIFIED GYNECARE TVT OBTURATOR SYSTEM
PRODUCT LIABILITY LITIGATION
vs. ETHICON, INC.
AND JOHNSON & JOHNSON
(Collectively referred to in this Report as Ethicon)

OPINION #4: The TVT Obturator System (TVT-O) Was Misbranded as a Result of False or Misleading Labeling.

The definition of "false or misleading" is not confined to meaning untrue, fraudulent, or deceptive. Labeling can be deemed by FDA to be misleading and in violation of FDA requirements if it proves deceptive to the customer by creating or leading to a false impression in the mind of the reader. Failure to inform the consumer of facts relevant to statements actually made may cause a "false impression," such that labeling that remains silent concerning certain consequences may be as deceptive as labeling that contains extravagant claims.[622]

Ethicon utilized promotional labeling that was false and misleading and failed to reveal material facts. This constituted misbranding. The introduction or delivery for introduction into interstate commerce of any device that is misbranded is a violation of Section 301(a) of the FDCA.[623] Thus, Ethicon deviated from the standard of care required of a medical device manufacturer by the multiple ways in which the TVT-O device was misbranded, including professional and patient labeling and also promotional labeling that was false and misleading in its representations and/or failed to include known or knowable safety information.

OPINION #5: Ethicon Failed to Meet the Postmarket Vigilance Standard of Care and Manage Risk, and The TVT Obturator System Was Thus Misbranded.

Ethicon failed to implement consistently effective and objective due diligence in the evaluation of complaint reports in order to manage potentially evolving risks, minimizing or negating the contribution of the TVT or TVT-O device as a potential factor in a number of adverse event reports. Thus, MDR reports for MDR-reportable events were not submitted to FDA as required by 21 CFR Part 803, Subpart E. Ethicon also failed to follow up to learn the outcome of adverse events unresolved at the time of reporting or at the time determined not to be MDR-reportable. In my professional opinion, Ethicon deviated from the standard of care by its failure to report to FDA a number of adverse events that met the criteria for Medical Device Reporting, rendering the TVT/TVT-O devices misbranded as a result of failure to furnish information requested under Section 519 of the FDCA.[624] The FDA depends on the manufacturer's cooperation and compliance with the Medical Device Reporting regulations to protect the public health.

XII. CONCLUSIONS

Based on my professional experience, knowledge, and training and my review, evaluation, integration, and synthesis of the information identified and discussed in this Report, including the materials and scientific/medical literature specified in Appendices B and C and information presented in Exhibits 1 through 4, it is my professional opinion, to a reasonable degree of scientific and professional probability, that Ethicon violated those duties required of a reasonably prudent medical device manufacturer.

The TVT Obturator System (TVT-O) devices were misbranded due to multiple labeling issues, including false and misleading information, inadequate directions for use, specifically, inadequate

[622] Medical Devices: Labeling Requirements – Misbranding (Available at www.fda.gov).
[623] 21 U.S.C. § 331(a).
[624] FDCA § 502(t).